Risk Management Commentary
for
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I. Presidential Objectives:

1. The very best science should determine the allocation of resources. Public fears drive much of regulatory and Congressional actions. These public concerns are often inconsistent with science-based selection of those factors most effective in improving public health.

2. Coherent policies, methodologies, and procedures for establishing regulatory objectives of the federal agencies on a scientific basis. These should effectively incorporate current science, peer review, and public participation.

3. Maximize the effectiveness of our huge national expenditures arising from regulations for improving health and safety by a balanced allocation of priorities and resources.

4. Minimize congressional prescriptions on details of risk management to give the agencies more flexibility to meet regulatory objectives with minimal impact on economic activities.

II. Recommendations:

1. Appoint a deputy for a full-time focus on Risk Assessment and Management. Select someone who understands the complexities of the issues.

2. Establish a Council (or PCAST Subcommittee) on Risk Assessment and Management for review and guidance of agency criteria, methodologies and procedures. This would provide scientific oversight on proposed agency activities and regulations. It would also coordinate the large number of existing government committees and programs already engaged on specific agency tasks.

3. Coordinate with OMB on the process for economic evaluations and agency implementation of OMB procedural recommendations.

4. Initiate a public education program on the realities of risks and choices (both governmental and individual), comparative risks, benefit-risk balance, and the acceptability of low-level exposures in daily life. The Society for Risk Analysis may be a vehicle for such a program. Modest financial support would be needed for workshops, bulletins, teaching material, etc.

III. Background Issues:

The cumulative national direct cost burden of proposed reductions of environmental risks is likely to exceed $100 billions per year (e.g. clean air, toxic, CFCs, CO2, electricity fields, house radon, hazardous waste, etc.). Indirect costs will increase this burden. These costs will become publicly apparent through their large inflationary effect on costs. They cannot be ignored. Unfortunately, there is no upper bound to such expenditures as long as "zero" risk is the political target, except a national resource limitation. Recognizing that poverty is the greatest social pollutant, the effect on the productivity of the economy must be considered.

Congress has implied in several acts that the cost of meeting health and safety objectives should not be considered in setting regulatory objectives. However, this does not preclude the establishment of regulatory targets consistent with the optimal distribution of our resources to improve health and safety. This is a central issue, as it is the operational intersection of risk assessment with risk management. Even a crude disclosure of the relative importance of risks might diminish the prescriptive tendencies of Congress, and shift the decision initiatives to the agencies on the allocation of funds and attention.

Public confidence in the wisdom, objectivity, credibility, and feasibility of government regulatory actions is an essential objective. This requires that the suggested OSTP Council be broadly based with expertise from all stakeholders (academia, government, industry, public groups, etc.) and is constituted to consider risk assessment, management, and communication. Obviously, such a Council would need staff support for organizing briefings, discussions, and fundings.

IV. Risk Assessment:

The quantitative establishment of the relationship between public exposure to a hazard and its health and safety consequences suffers from several handicaps.

1. Analytic uncertainties become larger as the exposure levels per person becomes smaller because the data base becomes vague and finally nonexistent. At the same time, the number of people involved tends to increase, so the cumulative public risk becomes indeterminate. As a substitute for scientific information, agencies use simplified extrapolations of high level data and "worst case" projections for regulatory purposes.

2. The agencies treat each hazard as an independent source of risk, and use fixed criteria for setting targets (e.g. EPA's 1 in a million lifetime risk). Comparative risk analysis is generally absent, although implicit balancing of the public perceptions of the relative importance of risks is subconsciously involved in agency attention.

3. The "worst case" syndrome pervades agency decisions. Given the uncertainties of the data, it is easier to publicly defend a "worst case" choice. However, the economic consequences may be extremely large, particularly when orders of magnitude are involved.

4. It is impossible to consistently use "worst case" analysis. Agencies tend to apply "worst case" projections to selected situations they choose to analyze, and to ignore the actual risks of unanalyzed hazards. This tends to make regulation arbitrary, capricious, and independent of the actual risk.

V. Risk Management:

1. There are no generally accepted measures as yet developed to compare the unlike consequences of a variety of risks (e.g. life threatening vs physical impairment, human vs ecologic, physical vs psychological, short term vs long term, etc). Nevertheless, such implicit evaluations are being made, and are shaped by the cultural biases of the decision makers.

2. There are no guidelines for comparative cost-effectiveness of the remedial measures imposed by regulations to achieve improvement in health or ecology, or of the reduction of involuntary exposures to risks. Regulations

are usually justified on the basis of individual risk reductions, without reference to the comparative cost-effectiveness of other risk reduction measures.

3. The responsibility for the implementation of risk management is shared in practice between government, industry, and the public. This is a very complicated interaction and can only be successful if all sectors agree on the objectives. In this respect, the Nuclear Regulatory Commission has pioneered in a sharing of responsibilities with the industry. It should be studied as a developing risk management system.

4. The individual exposure to risks arises from food, water, air, industry, life-style systems, work, etc. Many federal agencies are involved (FDA, EPA, NRC, HHS, OSHA, DOE, DOD, DOT,etc). The need for an Executive Office guidance and overview has been growing during this past decade.

5. The financial consequences of risk management regulations may be one of our largest national cost factors, indirectly comparable to health services and defense. It requires a scientific basis for rational decision making. It deserves OSTP attention at the highest level.

6. The Senate version of the Clean Air Act, S.1630, contains a long section on the establishment of a 10 member Risk Assessment and Management Commission. As presently proposed, this Commission reports to the President and Congress. It is intended to have a 4 year life. If this legislation is passed, its relationship to PCAST and the OSTP should be considered. This proposed Commission is focussed on air pollution., The OSTP interest should encompass the wider spectrum of risks covered by other federal agencies.

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